ACCEPTANCE SPEECH
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CHAIRMAN, SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
BEFORE THE
EMPIRE STATE PHARMACEUTICAL SOCIETY
SEPTEMBER 12, 1987

It is a distinct honor to receive the Empire State Pharmaceutical Society's "Man of the Year" award. I regret that my Congressional responsibilities in Washington have prevented me from attending in person to accept your award and enjoy your company.

My absence does not diminish the importance I attach to your recognition of my work in the Congress. I deeply appreciate this award.

I also regret that I could not join you because I am confident that your convention would have provided me an opportunity to learn much about pharmacy from you, first hand.

Pharmacists have a reputation in Washington of being public-minded. As you can imagine, there are many health issues which affect you only indirectly, but which are vital to many citizens. Your representatives have helped in the efforts to improve health care for all Americans.

Your involvement is critical because the health problems facing our country are many. There are four of particular concern to me.

- There are 37 million Americans with no form of health insurance. Even though many are poor, they do not get even the meager benefits of Medicaid. Surprisingly, many of the uninsured work in low-paying part- or full-time jobs.

- The AIDS epidemic races ahead jeopardizing the lives of millions in this country and abroad. While the death toll mounts, we at least are beginning to see some signs of progress in drug therapy and our understanding of the disease itself. We are not even remotely prepared, though, for the huge costs of treating the thousands of new patients who will become hospitalized.

- Health care costs for all of us continue their rapid rise despite record low inflation. And to make matters worse, our efforts to hold down hospital and doctor costs have increased the use of other services, like nursing homes and home health care, that are not covered by insurance. And as prescription drug therapies gain in importance in treating illnesses -- and the prices of those drugs continue to increase -- out-of-pocket health care costs rise dramatically.

- Our rapidly aging population will present the health care

system of the 21st century with overwhelming new demands that we are not prepared to meet. We talk of "catastrophic" health insurance for the aged, yet too many leave out coverage for nursing home care and drugs. Several years in a nursing home or a decade of $200 a month drug costs are no less a medical and financial catastrophy than a prolonged hospital stay.

These issues will be in front of us for years to come. Others, which more directly affect your profession and your businesses, have been addressed in the last two years in the Congress.

Allow me to take a few moments and discuss the legislative activity that I have been involved in that affects pharmacists and pharmacy.

MEDICARE CATASTROPHIC PRESCRIPTION DRUG COVERAGE

Perhaps the most newsworthy has been the Medicare Catastrophic bill. As you may know, the House of Representatives has passed the bill with a new prescription drug benefit for Medicare beneficiaries. This is one of the many improvements made in the Administration's bill.

I congratulate Dr. Bowen, the Secretary of the Department of Helath and Human Services, for putting catastrophic coverage under Medicare on the agenda for this Congress. But there are serious limitations in the Administrations's approach. One of those is in the area of catastrophic drug costs. Along with long term care expenses, drug costs are one of the gaps in Medicare that our senior citizens are most anxious to have addressed.

Outpatient prescription drugs are not currently covered by Medicare, with the exception of immunosuppressive drugs needed by an organ transplant recipient. This imposes a substantial burden on enrollees. The elderly use 30 percent of all prescription drugs in this country, and use them roughly three times the rate of the non-elderly. Many have chronic conditions that require them to take expensive medications on a regular, sustained basis in order to remain alive or to maintain their level of functioning.

Under the House-passed bill, Medicare would cover 80% of the cost of all outpatient prescription drugs that are approved as safe and effective by the Food and Drug Administration, after the enrollee had incurred $600 in expenses for such drugs in a year. Insulin would also be covered. Payment would be the pharmacy's actual charge, subject to specified limits calculated for each drug.

If a generic drug has been approved by the FDA, payment could not exceed the limit for generics, unless the prescribing physician indicated in handwriting that a brand name drug was necessary.

The bill introduces the concept of "participating pharmacies". These pharmacies would sign an agreement not to charge Medicare patients more than the general public, to assist enrollees in

determining whether their $600 deductible had been met, to file information to that effect on behalf of the enrollee with Medicare, to accept assignment on all subsequent prescriptions, and to counsel enrollees on generics and proper drug use.

This benefit would be financed entirely by additional premiums, paid by Medicare Part B enrollees.

I believe the time has long since come for Medicare to provide coverage for catastrophic drug costs. I urge all of you to join with the groups representing the elderly in this country and to work with us to assure passage of this important legislation.

PHYSICIAN DISPENSING

In an editorial on March 28, 1987, under the heading "Doctors Shouldn't be Pharmacists," the New York Times posed some difficult questions:

> The physician/pharmacist has an obvious potential conflict of interest. Might he be tempted to write unnecessary prescriptions? Or to prescribe a drug he sells when another he doesn't sell might be preferable? Or to sell brand-name drugs with high markups when cheaper generics are available?

These questions go directly to the ethics of medical practice. In our fee-for-service system, the immediate financial incentives favor performing medical services that have their own fees. But at least those services are principally medical ones, involving the skill and judgment of a physician.

When it comes to the act of selling a drug after a patient has been examined and a diagnosis and course of treatment has been decided on, however, the question concerns pharmacy and business.

There are checks and balances in the current system. Professional licensed pharmacists provide a level of additional professional judgment. After leaving the doctor's office, patients can act as informed consumers in pharmacies, which are a marketplace for price competition.

The Subcommittee on Health and the Environment, which I chair, and the Committee on Energy and Commerce have passed legislation responding to these concerns.

The bill is H.R. 2168. It prohibits practitioners who are licensed to administer drugs from dispensing prescription drugs for their own profit, except in certain circumstances. Violations of the bill would be considered prohibited acts subject to the penalties under the Federal Food, Drug, and Cosmetic Act.

The prohibition does not apply to the dispensing of an oral drug or a vaccine, or in an emergency or other situation when a patient

would have substantial difficulty in obtaining drugs from a pharmacy, or in rural areas. The prohibition does not apply to the delivery of a drug through a licensed pharmacy pursuant to a prescription of a practitioner.

The bill also provides that neither it nor any other Federal law preempts or supersedes any State law or regulation which regulates the terms and conditions of, and the charges which may be made for, the dispensing of drugs by licensed practitioners. This is intended to permit states to exercise jurisdiction over drug dispensing, if they so choose.

The future of H.R. 2168 is unclear. So far, there has been no action in the Senate. I believe this bill ought to become law.

DRUG DIVERSION

Another bill that I know is of interest to pharmacists is the "drug diversion bill" or the "Prescription Drug Marketing Act of 1987".

This bill, H.R. 1207, is being considered by the Senate.

This bill is intended to eliminate a "grey market" for prescription drugs that has developed in this country. Drugs have been manufactured and distributed for one purpose and diverted into the "grey market." This has included drugs intended for export, for distribution as samples, and for use by the patients of hospitals and other health care entities.

The bill creates new provisions in the Federal Food, Drug and Cosmetic Act. It would generally prohibit the reimportation of pharmaceuticals exported from the United States, the selling, trading, or purchasing of drug samples, the transacting in or counterfeiting of coupons for prescription drugs, and the resale by hospital and other health care entities of pharmaceuticals they have purchased. Exceptions are made for emergencies, and health care entities are permitted to transfer drugs within the umbrella of a group purchasing organization.

Manufacturers or distributors may distribute drug samples only by the methods authorized in this bill, which include numerous provisions to assure that samples are properly stored and are not sold. One permissible method of sample distribution is to do so through mail or common carrier, and another would continue to permit distribution directly by employees or agents of the manufacturer. Both methods require a written request from a licensed practitioner and the keeping of detailed records. Drug distributors must be licensed by states for the first time.

ANTI-GENERIC CAMPAIGN

In 1984, Congress made the most important changes in the Federal

Food, Drug and Cosmetic Act in the last twenty years. The Drug Price Competition and Patent Term Restoration Act, or the so-called "generic drug law", established an expedited approval system for generic copies of off-patent brand name drugs. And in addition, it extended drug patents for up to five years to restore patent term lost while getting FDA approval.

When the President signed the generic drug law in September 1984, he proclaimed a day when "the American people will save money, and yet receive the best medicine that pharmaceutical science can provide." The President echoed an optimism shared by all in the Congress who worked on the legislation.

The brand name drug companies supported the 1984 law. Since then, many have shifted tactics.

Some of the many large research-oriented companies are buying generic firms or starting their own generic divisions. Others are engaging in an anti-generic campaign calculated to discourage generic use and boost corporate revenues.

After securing the patent extension rules they sought, some brand name companies have quietly turned their advertising and public relations experts loose. After making most of the generics that had been consumed for 20 years prior to passage of the new law, some brand-name companies now claim that the approval system does not protect the public from unsafe or ineffective generics.

In some states it appears that the anti-generic campaign may be working. Brand companies are successfully influencing some physicians to prescribe brand-name drugs only. Those doctors are prohibiting pharmacists from substituting therapeutically equivalent generics.

In the short run, an anti-generic campaign may work. But, an industry that makes generics in private while lambasting them in public will eventually lost credibility and reputation. To think otherwise is cynical and short changes the American people.

The impact of the 1984 generic drug law is just beginning to be felt. As insurance companies, HMOs, hospitals, and state and federal programs become familiar with possible savings, many will shift to generic products. Acceptance by the public is inevitable.

PRESCRIPTION DRUG PRICES

In coordination with the anti-generic theme, brand name companies have also raised their prices at unprecedented rates. The public and the health care system are the losers, and pharmacists are often the ones caught in between.

It appears to me that in 1981 brand-name companies embarked on a new pricing strategy. It is called "whatever the market will bear". Unfortunately, when it comes to essential prescription drugs, consumers

have no choice. They will bear whatever is charged by the companies.

And consumer costs have skyrocketed. At my Subcommittee's April 21, 1987, hearing, we documented the unprecedented rise. Between 1981 and 1986, the CPI increased 28 percent. During the same time, drug manufacturer wholesale prices rose over 79 percent. Many of the top-selling brand-name drugs rose even faster.

Incredibly, this 79 percent rate actually understates brand-name drug price increases. The government's drug price figures include generic drugs, whose prices have been falling dramatically. If we could separate brand-name drug price increases, they would greatly exceed 79 percent for the six year period.

The brand-name companies argue that these price increases are necessary to fund their fast-rising costs for research and development. To evaluate their claim, the Subcommittee surveyed the 25 largest companies with 2/3 of all prescription drug sales in the U.S.

For the years 1982-1986, we found that revenue gains due to price increases were 3 times greater than their total increase in R & D expenditures. We also found that the companies spent as much on marketing as on R & D.

The conclusion is inescapable -- the recent price increases are not producing new drugs. They are filling corporate coffers.

In the immediate future, the public and the health care system are the losers from higher prices. With time, though, I have no doubt that brand-name pharmaceutical companies will suffer. Their image as caring for the patients treated by their drugs is already tarnished. At some point, the public will turn to government for help.

There are many health care issues in the Congress. These are some of the more important ones.

In closing, let me again say how much I appreciate this award. My best wishes to your Society and your membership.